UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH & LOMB INCORPORATED and BAUSCH + LOMB IRELAND LIMITED, Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No. 23-00790 (MEF) (JRA) (CONSOLIDATED)

STIPULATION AND [PROPOSED] ORDER
REGARDING LIMITATIONS OF CLAIMS AND DEFENSES

WHEREAS Plaintiffs Bausch & Lomb Incorporated and Bausch + Lomb Ireland Limited (collectively, "Bausch" or "Plaintiffs") and Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin" or "Defendants"), seek to reduce the scope of the consolidated above-captioned case (the "Action") in order to conserve their and the Court's resources;

NOW THEREFORE, Plaintiffs and Defendants, subject to the Court's approval, hereby stipulate and agree as follows:

1. Lupin Ltd. has submitted Abbreviated New Drug Application No. 218087 ("Lupin's ANDA") seeking approval to market the generic loteprednol etabonate gel, 0.38% product described therein ("Lupin's ANDA Product").

2. Plaintiffs assert in this Action that Defendants infringed claims 1–17 of U.S. Pat. Nos. 10,596,107 (the "'107 patent") and claims 1–8 of 11,534,395 (the "'395 patent") (collectively, the "Asserted Claims") under 35 U.S.C. § 271(e)(2) by submitting Lupin's ANDA, and would also infringe the same claims (directly or indirectly) under 35 U.S.C. § 271(a)–(c) by making, using, offering to sell, or selling Lupin's ANDA Product.

3. Without prejudice to Lupin's positions regarding the invalidity of the Asserted Claims, Lupin stipulates that Lupin's ANDA is for a drug product claimed in a patent or the use of which is claimed in a patent and that the submission of Lupin's ANDA to the FDA was an artificial act of infringement of the Asserted Claims under 35 U.S.C. § 271(e)(2).

4. Without prejudice to Lupin's positions regarding the invalidity of the Asserted Claims, Lupin stipulates that the manufacture, use, offer to sell, sale, and/or importation of Lupin's ANDA Product would infringe each of the Asserted Claims in this Action under 35 U.S.C. § 271(a)–(c) to the extent that the Asserted Claims are not found to be invalid and/or unenforceable.

5. This Stipulation does not itself entitle Plaintiffs to a judgment of infringement or any other relief, including any relief under 35 U.S.C. § 271(e)(4). Any such relief will be entered upon the issuance of a judgment in this Action finding at least one asserted claim not invalid. The parties reserve all rights to seek or oppose additional remedies. For clarity, nothing in this section shall be construed to limit use of this Stipulation in the event Plaintiffs seek a preliminary injunction.

6. The parties agree to act in good faith to use their best efforts to streamline discovery related to remaining issues in this Action.

7. Bausch agrees that it will not seek written discovery, in the form of Interrogatories, Requests for Admission, or Requests for Production, from Lupin, other than those provided for in ¶ 8 of this Stipulation. The parties agree that they will not seek production of electronically stored information (ESI) pursuant to a formalized ESI protocol in discovery. For clarity, responsive information and documents that have been or are currently electronically stored are not exempt from discovery solely because the information and documents have been

or are currently maintained in electronic form.

8. Bausch retains the ability to propound limited and focused written discovery, including, Interrogatories, Requests for Admission, or Requests for Production, on the following subject matter: (i) the process for identifying and selecting (a) the concentrations of excipients used in Lupin's ANDA Product, and (b) the particle size specifications for Lupin's ANDA Product, including all testing and analysis related to (a) and (b), and (ii) the process for milling loteprednol etabonate particles used in Lupin's ANDA Product, to the extent such discovery relates to issues of validity and/or objective indicia of non-obviousness.

9. Bausch may propound a Notice of Deposition to Lupin under Federal Rule of Civil Procedure 30(b)(6) and take the deposition(s) of any designated Lupin witness(es). Bausch's Notice of Deposition will be limited to topics falling within the subject matter described in ¶ 8 herein. Deposition testimony of a Lupin witness under Federal Rule of Civil Procedure 30(b)(6) will also be permitted to the extent necessary to authenticate any document(s).

10. Bausch agrees that it will not seek fact depositions of Lupin, Lupin's employees, or Lupin's former employees under Federal Rule of Civil Procedure 30(b)(1) during the remainder of this Action.

11. In the event a previously unforeseen factual development arises in the case (including, without limitation, a potential launch at risk by Defendants) the parties will meet and confer in good faith about Bausch's ability to seek additional discovery on that topic. If the parties are unable to reach resolution, they will jointly prepare a letter to put this issue to the Court.

12. Lupin agrees that documents within the Bates Range Lupin_Lote_0000001–0026002 are authentic and genuine copies of Lupin's ANDA and correspondence with the FDA regarding Lupin's ANDA.

13. Lupin agrees to further stipulate to the authenticity, in the same manner as set forth in ¶ 12 above, of any documents submitted to the FDA in support of its ANDA, including of any correspondence between Lupin and the FDA in connection with Lupin's ANDA, which (i) have not yet been produced to Bausch but (ii) are produced to Bausch after the date of this stipulation.

14. For any other documents produced by Lupin, Lupin agrees either to stipulate as to their authenticity, or to make a Lupin witness available for deposition such that Bausch may seek to have the document(s) in question authenticated.

15. For any documents produced by Bausch, Bausch agrees to stipulate as to their authenticity, or to make a Bausch witness available for deposition such that Lupin may seek to have the document(s) in question authenticated.

16. No party shall present any testimony, from any fact or expert witness, on the issue of infringement by Lupin's ANDA Product at trial.

Dated: April 5, 2024

s/ William P. Deni, Jr.
William P. Deni, Jr.
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, NJ 07102
(973) 596-4500
wdeni@gibbonslaw.com
jlower@gibbonslaw.com

OF COUNSEL:

Thomas P. Steindler (*pro hac vice*)
April E. Weisbruch (*pro hac vice*)
Christopher M. Bruno (*pro hac vice*)
MCDERMOTT WILL & EMERY LLP
500 North Capitol Street N.W.
Washington, D.C. 20001
(202) 756-8000

Attorneys for Plaintiffs
Bausch & Lomb Incorporated and
Bausch + Lomb Ireland Limited

s/ James S. Richter
James S. Richter
MIDLIGE RICHTER, LLC
645 Martinsville Road
Basking Ridge, New Jersey 07920
(908) 626-0622

OF COUNSEL:

Kurt A. Mathas (*pro hac vice*)
Katherine Kyman (*pro hac vice*)
Annie Steiner (*pro hac vice*)
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
(312) 558-5600

Claire Fundakowski (*pro hac vice*)
Sharon Lin (*pro hac vice*)
WINSTON & STRAWN LLP
1901 L Street NW
Washington, D.C. 20036
(202) 282-5000

Attorneys for Defendants
Lupin Ltd. and Lupin Pharmaceuticals, Inc

SO ORDERED this 8th day of April, 2024

Honorable Michael E. Farbiarz, U.S.D.J.